

**UNITED STATES OF AMERICA
BEFORE THE FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES**

9112 '02 DEC 19 P4:05

In the Matter of:

**Enrofloxacin for Poultry:
Withdrawal of Approval of
New Animal Drug Application
NADA 140-828**

FDA DOCKET: 00N-1571

Date: December 19, 2002

**RESPONDENT BAYER CORPORATION'S RESPONSE TO CVM'S REQUEST
FOR CLARIFICATION OF THE APRIL 26, 2002 SCHEDULING ORDER
AND CLARIFICATION OF DECEMBER 3, 2002 ORDER**

Respondent Bayer Corporation ("Bayer") hereby responds to CVM's December 18, 2002 Request for Clarification.

Bayer's Response to CVM's Request for Clarification 1: CVM should be required to submit rebuttal, if any, well before January 27, 2003. The record is clear that Bayer was given only 4 calendar days, from December 9, 2002 to December 13, 2002 to attempt to respond to the testimony of CVM's 35 witnesses.¹ By the time CVM receives "clarification," it will already have had more time to respond to less testimony. CVM has had the April 26, 2002 Order for nearly 8 months and waited until after Bayer's testimony to seek clarification of rebuttal deadlines. Now, in the name of "preserving resources," CVM does not want to be required to respond to Bayer's and AHI's combined 26 witnesses, if at all, until more than 45 calendar days have expired. All of this flies in the face of CVM's plea back on April 25, 2002; "As a matter of fundamental

¹ As noted by the vast majority of Bayer's witnesses addressing CVM's testimony, they did not have an opportunity to study and fully respond to CVM's testimony given the short turn around time.

fairness, it is not appropriate to treat the parties differently with respect to the time available to prepare their respective cases.” (CVM’s Response in Opposition to Bayer Corporation’s Motion to Amend Schedule of Due Dates, April 25, 2002, p. 6). Anyone reviewing this record can draw its own conclusion as to the “fundamental fairness” by weighing 4 days against 45 or more.

As a practical matter, CVM’s proposal to submit rebuttal after January 27, 2003 will upset the current schedule and raises scheduling questions. Will there be a separate set of motions to strike and to request cross-examination of CVM’s rebuttal witnesses? When will those be due? How will that fit with the remaining schedule?

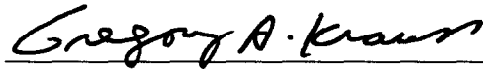
The fair and practical solution is to require CVM to submit rebuttal testimony, if at all, by some date well in advance of the January 27, 2003 deadline for motions to strike and requests for cross-examination.

Bayer’s Response to CVM’s Request for Clarification 2: CVM’s rebuttal testimony should be in the form of written direct testimony and should be subject to oral cross-examination.

Bayer’s Response to CVM’s Request for Clarification 3: For the reasons set forth above, CVM should be required to submit rebuttal testimony well before January 27, 2003. For example, requiring rebuttal by January 6, 2003 gives CVM ample time, still allows Bayer an opportunity to move to strike or request cross-examination of CVM’s rebuttal testimony, and preserves the current schedule. Even considering the holiday season, this gives CVM more than 3 times the amount of time Bayer was given to respond to CVM’s testimony.

Bayer's Response to CVM's Request for Clarification 4: Bayer's December 9, 2002 submission demonstrated facts sufficient to add Dr. Harris to Bayer's witness list. Bayer believes Dr. Harris' testimony should now proceed on the same schedule as all other Bayer witness. It is worth noting that CVM has had Dr. Harris' report since November 29, 2002.

Respectfully submitted, this 19th day of December by:

A handwritten signature in black ink, reading "Gregory A. Krauss", is written over a horizontal line.

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Attorneys for Bayer

CERTIFICATE OF SERVICE

I hereby certify that a copy of Respondent Bayer Corporation's Response to CVM's Request for Clarification of the April 26, 2002 Scheduling Order and Clarification of December 3, 2002 Order was e-mailed and also mailed, postage pre-paid, this 19th day of December, 2002 to:

Kent D. McClure
Animal Health Institute
1325 G Street, N.W., Suite 700
Washington, D.C. 20005

Nadine R. Steinberg, Esquire
Food and Drug Administration
Office of General Counsel (CGF-1)
5600 Fischers Lane, Room 7-77
Rockville, MD 20857



Gregory A. Krauss

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December 19, 2002

VIA HAND DELIVERY

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane (Room 1061)
Rockville, Maryland 20852

Re: In the Matter of Notice of Hearing: Proposal to Withdraw
Approval of New Animal Drug Application for Enrofloxacin
for Poultry ("Enrofloxacin Hearing")
FDA Docket: 00N-1571

Dear Sir/Madam:

Enclosed for filing please find an original and two copies of Respondent Bayer Corporation's Response to CVM's Request for Clarification of the April 26, 2002 Scheduling Order and Clarification of December 3, 2002 Order. Please return a file-stamped copy in the enclosed self-addressed stamped envelope.

Please call with any questions.

Sincerely,



Gregory A. Krauss

GAK:jeh
Enclosures